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AMERICAN BOARD
NEUROLOGICAL SURGERY

509-453-i 969

November 29. 1999

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir/Madam:

DOCKET # 97N-4845
FDA Proposal to Regulate Allograft Tissue

I have been asked to comment on the proposed FDA regulation that could and, hopefully, would regulate allograft application for Orthopedic or Neurosurgical procedures requiring stabilization.

There is little question that the ratio of graft rejection and/or pseudarthrosis, even much later, is demonstrably higher in allografts than in homografts.

The added time and effort required in homograft harvesting is very small, particularly considering the substantially higher percentage of take (fusion).

"Banked bone" grafts should, obviously, be carefully regulated, not only with regard to early rejection, but also to their fate (non-fusion) several years later and, therefore, should probably be reserved for those rare cases where harvesting from the patient is contraindicated.

Sincerely yours,

C. M. Gottlieb, M.D.

CMG:rn

97N-4845

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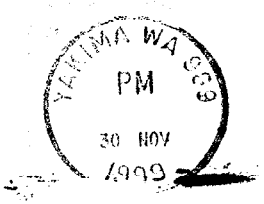

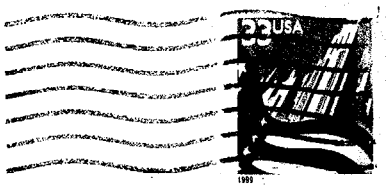

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